Testimony on the EPA Proposed Decision on Particulate Matter

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My name is Suresh Moolgavkar. I am a physician with a Ph.D. in Mathematics, and post-doctoral training in Epidemiology and Biostatistics. I am currently a Full Member of the Fred Hutchinson Cancer Research Center and Full Professor of Epidemiology and Adjunct Professor of Biostatistics at the University of Washington in Seattle. I have more than 20 years of experience in Epidemiology, Biostatistics and Quantitative Risk Assessment. Over the last several years I have studied carefully the epidemiologic literature on particulate matter, and have also conducted independent analyses of the epidemiologic data.

The proposed new regulations for particulate matter are based on the assumption that the magnitude of the associations between these pollutants and adverse human health effects reported in some epidemiologic studies is predictive of the gains in human health that would accrue by lowering ambient concentrations. The evidence simply does not support this assumption. Briefly, the dearth of toxicological information, the absence of biological understanding of underlying mechanism, and the potential for uncontrolled confounding by copollutants currently preclude the conclusion that the particulate component of air pollution is causally associated with adverse effects on human health.

Although the EPA pays lip service to these uncertainties in its Proposed Decision, the language supporting the new regulations espouses a certainty that is simply not warranted by the data. This is particularly true of the proposed annual standards for fine particles. There are few epidemiologic studies using direct measurements of fine particles. The annual standard is based largely on the Six Cities and the ACS II studies. While the EPA labels these studies prospective cohort studies, they retain crucial aspects of the ecologic design, and suffer from many of the deficiencies of ecologic studies. For example, the exposure of primary interest, air pollution, is not measured on individuals. Rather information is available only on a population basis from regional monitors. Moreover, confounding is more difficult to control than in time-series studies. In particular, even important confounders, such as weather, have not been controlled in these studies. Thus, these studies greatly overstate the statistical significance, and overestimate the magnitude of the association, between components of air pollution and mortality. More details regarding my serious reservations about these studies can be found in a recent publication (Moolgavkar and Luebeck, 1996).

The EPA makes much of the consistency and coherence of the epidemiologic studies of particulate air pollution, pointing out that a number of studies in the peer-reviewed literature report associations between particulate air pollution and effects on human health. Peer review is no guarantee of the veracity of the results reported in a paper, however. No reviewer can reanalyze the data to ensure that subtle biases in interpretation of analyses have not crept in. This is particularly true when statistical analyses are complex and reported effects are small, as in studies of air pollution. It is

instructive to note in this regard that some of the data have recently been reanalyzed by other reputable investigators. In every case, the interpretation of these reanalyses has been quite different from that of the original investigators. At least two new and separate analyses (HEI, 1996; Moolgavkar and Luebeck, 1996) of the mortality in Philadelphia, controlling confounding by copollutants much more carefully than the original papers, have concluded that, although air pollution is associated with daily mortality, the particulate component cannot be singled out. A reanalysis (Davis et al., 1996) of mortality in Birmingham concludes that, when humidity is controlled, particulate matter is no longer significantly associated with mortality. A reanalysis (Moolgavkar et al., 1997) of hospital admissions in Minneapolis also concludes that the association between air pollution and hospital admissions cannot be attributed specifically to the particulate component. A similar analysis (Moolgavkar et al., 1997) in Birmingham shows no association between air pollution and hospital admissions. Yet, EPA chooses to ignore the wider implications of the new studies, preferring, instead, to take a head count of 'positive' and 'negative' studies.

An important casualty of the highly charged debate about standards for particulate matter is scientific integrity. Air pollution is a complex mixture. It flies in the face of elementary pathophysiologic considerations to think that single components of air pollution could be acting independently of one another. Yet, driven largely by the regulatory imperative, epidemiologic studies have focused on single components of the mixture. From the practical point of view, perhaps the saddest legacy of the reductionist approach is that, by mandating a tough new standard for particulate matter, the EPA is

precluding a more flexible regional air pollution strategy based on consideration of air pollution as a whole. With levels of air pollution generally declining in the U.S., we do not know to what extent improvement in air quality has led to improvement in health. What is required at this time is, not new and more stringent standards, but research to evaluate the impact of improving air quality on human health. Such an evaluation, while difficult to do, would allow better estimation of health benefits, if any, that could be expected to accrue from further strengthening of standards, and should be undertaken before draconian new control measures are imposed.

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